NOV 2 0 2001

K011963

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Glucose Hexokinase II method for Bayer ADVIA® 1650 System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K011963**

1. Intended Use

The Glucose Hexokinase II in vitro diagnostic procedure is intended to measure glucose in human serum, plasma and urine on the Bayer ADVIA® 1650 System. Such measurement is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and insulin overdose.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #	Predicate Device #
ADVIA 1650 Glucose Hexokinase	B01-4129-01	T03-1291-62	K991576

3. Device / Method

Product Name	REF	Calibrator Part #
ADVIA 1650 Glucose Hexokinase II	04903429	T03-1291-62

A. Imprecision

ADVIA 1650 Glu Hex II				ADVIA 1650 Glucose Hexokinase		
Specimen type	Level (mg/dL)	Total CV(%)		Specimen type	Level (mg/dL)	Total CV(%)
Serum	75	2.2		Serum	77	2.4
Serum	279	2.2		Serum	279	3.3
Urine	46	4.1		Urine	42	3.5
Urine	267	3.6		Urine	285	3.6

Correlation (Y=ADVIA 1650 Glucose Hexokinase II, X=ADVIA 1650 Glucose Hexokinase)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
Serum	ADVIA 1650	194	Y=1.02x-1.84	7.49	0.998	49.3-589.8
Urine	ADVIA 1650	99	Y=0.97x-7.44	5.68	0.999	0.0-690.8
Plasma(y) vs Serum(x)*	ADVIA 1650 2 reagent method for both	35	Y=1.001x+0.088	5.33	0.9997	73.2-623.05

*spiked samples used

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Glucose (mg/dL	Effect (% change)
Bilirubin	29.1	81.32	1.05
Hemoglobin	522	80.6	0.78
Lipids (Intralipid)	630	80.2	-4.7

Analytical Range

Serum/Plasma/Urine: 0 to 700 mg/dL

Nonclinical testing demonstrates that this device is as safe and effective as the predicate device.

Table of Similarities and Differences between Glucose Hexokinase and Glucose Hexokinase II assay:

Package Insert Sections	Glucose Hexokinase assay (predicate device)	Glucose Hexokinase II assay
Intended Use	similar	similar
Summary	similar	similar
Principle	similar	similar
Reagents	Assay buffer in single aliquot for reaction	Assay buffer in dual aliquots. Formulation identical; new format allows for blanking.
Storage	similar	similar
Stability	25 days	Similar, actual dating TBD
Precautions	similar	similar
Indications of Deterioration	similar	similar
Performance Characteristics	similar	similar
Limitations	Blanking was impossible. Assay potentially susceptible to interferences.	Blanking now possible; interference effects eliminated
Parameters	similar	similar

The changes in the assay represent improvements and allow for blanking, with an aliquot of buffer, and hence subtraction of any potential interference effects.

9/25/01

Kenneth T. Edds
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth T. Edds, Ph.D.
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097

NOV 2 0 2001

Re: k011963
Trade/Device Name: Glucose Hexokinase II Assay for the Advia 1650
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CFR
Dated: September 25, 2001
Received: September 26, 2001

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 2 0 2001

510(k) Number: K011963

Device Name: Glucose Hexokinase II Assay for the Advia 1650

Indications for Use:

The Glucose Hexokinase II in vitro diagnostic procedure is intended to measure glucose in human serum, plasma and urine on the Bayer Advia 1650 system. Such measurement is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and insulin overdose.

Thomas C. Gruta

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011963

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)